DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

3/19/98

D1375B

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-20

January 15, 1998

J. Eduardo Miranda, President
Digicare Biomedical Technology, Inc.
6879 Vista Parkway, North
West Palm Beach, Florida 33411

Dear Mr. Miranda,

We are writing to you because on December 3 through 10, 1997, FDA Investigator Michelle S. Dunaway collected information that revealed serious regulatory problems involving the Digimax 5000 configurable, multiparameter, physiologic monitor and the Digipump model SR 2000 syringe infusion pump which are manufactured and exported by your firm.

Under the Federal Food, Drug and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

This inspection revealed that these devices have been illegally exported in violation of section 802(f)(1) of the Act, because the devices are adulterated within the meaning of section 501(h) of the Act in that the methods used in, or the facilities or controls used for manufacturing, processing, packing, storage, or installation are not in conformance with the CGMP requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot or batch of finished devices meets acceptance criteria, e.g., 16 units were released without documentation of the

post-burn-in acceptance test that is required in the device master record (DMR); four units (s/n 513341, 513342, 513347, 513348) were released since November 3, 1997 with leakage current test values above the specified 10 microampere (μA) limit on the ECG leads; a unit (s/n 513309) was released on or about June 10, 1997 without documentation of the production, post-burn-in, CRT, motherboard, and invasive pressure tests.

- Failure to establish and maintain procedures for receiving, reviewing, evaluating and investigating all complaints in a uniform and timely manner, e.g., Complaint dated October 2, 1997, states that the keyboard for a pulse oximeter (s/n 213816), "don't work". This unit was shipped on April 22, 1997. No investigation or record was made regarding this complaint describing the reason(s) no investigation was made. The corrective action for this complaint was to send a replacement keyboard to the complainant; Complaint dated August 19, 1997, states that 2 pulse oximeters with ECG, serial numbers not identified, have "gone out of order" and "we require the service manuals for repairing them". These units were shipped on January 3, 1997. No investigation or record was made regarding this complaint describing the reason(s) no investigation was made. The corrective action for this complaint was to mail 2 service manuals to the complainant; Complaint dated April 22, 1997 states "the pulse volume control potentiometer and the knob...are not installed..." and "...pulse bar graph display is not working..." for the Digipress blood pressure monitor (s/n 913458). The unit was shipped on March 26, 1997. No investigation or record was made regarding this complaint describing the reason(s) no investigation was made. The corrective action for this complaint was to send replacement parts to the complainant for repair of the unit; Complaint dated August 11, 1997, states "when used abruptly shoots to 250 beats/min while monitoring ECG and remains at 250 BPM" for a Digimax physiologic monitor in a neonatal care unit (s/n 513281). The unit was shipped on April 15, 1997. Troubleshooting guidance was provided to the complainant on August 11, 1997. On August 21, 1997, the complainant responded and said that they have had problems with the unit since it had been received. The complainant checked

the cables and also made a repair on the mother board but the problem remained. The board was returned and tested but no problems were found. A new board was shipped to the complainant and no additional problems have been reported. The results of the tests performed as part of the investigation were not documented.

- Failure to document in service reports and all necessary details of services performed, e.g., No service information, including the service performed, date performed, individual performing the service and the subsequent test and inspection data was documented for the services related to the complaints dated August 6 and September 15, 1997; No service information including the service performed, date performed, individual performing the service and the subsequent test and inspection data was obtained from the authorized service provider for services related to the complaints dated March 16 and August 19, 1997.

- Failure to establish and maintain procedures for the identification, documentation, evaluation and investigation, and, if applicable, the segregation and disposition of nonconforming, in-process devices, finished devices, and returned devices, e.g., four units (s/n 513341, 513342, 513347, 513348) were released with leakage current test values above the specified 10 μA limit on the ECG leads. No evaluation or investigation was made regarding these nonconformities; No evaluation or investigation was made regarding the nonconformities identified in the complaints dated April 22, August 19, and October 2, 1997; The results of the investigations regarding the nonconformities identified in complaints dated August 6, 11, and September 15, 1997 were not documented.

- Failure to ensure that all rework activities are documented in the device history record (DHR).

- Failure to review for adequacy and approve all documents maintained as part of the device master records (DMRs) prior to issuance, e.g., the Digimax 5000 monitor ECG board, CPU board, video section, serial board, motherboard and assembled unit test procedures are written in Portuguese, a language not understood by

current production personnel; and the leakage current test procedure used by production personnel is a photocopy from a text book, which identifies the specifications for maximum source current that can emanate from the patient end of the cables as "20 micro amperes for critical care areas and 50 micro amperes for other areas". However, another document in the device master record (DMR) identifies the leakage current specification as less than 10 μA at Vac/60Hz.

- Failure to establish and maintain procedures for implementing corrective and preventive action that includes requirements for analyzing processes, work operations, quality audit reports, service records, complaints, repair part usage and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems, to investigate causes of nonconformities, to identify actions needed to prevent recurrence of nonconforming product and other quality problems, and to verify or validate the adequacy of corrective and preventive actions, e.g., four units (s/n 513341, 513342, 513347, 513348) were released with leakage current test values above the specified 10 μA limit on the ECG leads. No evaluation or investigation was made to identify the root cause of these nonconformities and no action has been identified to correct and prevent recurrence of this failure mode; No investigation was made to identify the root cause of the nonconformities and no action has been identified to correct and prevent recurrence of the failure modes regarding the nonconformities identified in bullets 2, 3 and 4 above.

- Failure to establish procedures to ensure that equipment is routinely calibrated, inspected, checked and maintained, e.g., None of the inspection, measuring, test and calibration equipment is subject to a periodic calibration program including three oscilloscopes, three multimeters, a frequency counter, an ICR meter and two simulators; The Dynatech Nevada model MEDSIM 300 simulator, used during the acceptance activities for the Digimax 5000, has not been calibrated since April 28, 1993.

- Failure to establish, implement, maintain and conduct planned and periodic audits of the Quality Assurance program.

- Failure to maintain Device History Records (DHRs) for each batch, lot, or unit to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR), e.g., no device history records (DHRs) are available for the 8 digipump syringe infusion pumps that were manufactured, released and distributed in 1996.

You should be aware that section 519 of the Act requires manufacturers and distributors of medical devices subject to the Medical Device Tracking Requirements regulation as specified in 21 Code of Federal Regulations (CFR), Part 821 establish a medical device tracking system for the collection, recording, maintenance and auditing of tracking data for subject devices that include infusion pumps and breathing frequency monitors. The failure to do so may render such devices adulterated and misbranded within the meaning of section 502(t)(2) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Inspectional Observations (FDA 483) issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying

systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your fax'd response dated December 22, 1997 received in the Florida District Office on January 7, 1998 is inadequate to address the concerns from the December 3-10, 1997 inspection. You must provide written documentation of policies and procedures to substantiate that corrective actions have been implemented. We also note that all of your planned corrective actions will not be completed until March 31, 1998. Please provide updates for our review as they are made on a monthly basis until all of your corrections are made and you can assure that your firm has achieved substantial conformance with the Quality System Regulation.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 7200 Lake Ellenor Drive, #120. Orlando, Florida 32809.

Sincerely yours,

Edward R. Atkins

Edward R. Atkins
Acting Director
Florida District